Section II (Remarks)

Crossing in Mail of October 13, 2005 Preliminary Amendment and Office Action

At the outset, it is be noted that the Preliminary Amendment filed by applicant on October 13, 2005, introduced new claims 41-56, however, such claims were not addressed in the Office Action of the same date.

Accordingly, such added claims will be addressed in the ensuing remarks, in respect of the references cited as a basis for the various rejections of claims under 35 USC 102 and 103.

It is affirmatively stated that the subject matter of such added claims 41-56 relates to the subject matter of Group I provisionally elected on October 5, 2005.

Cancellation of Claims 1-19

Claims 1-19 have been canceled herein, to advance the prosecution of the application to allowance of claims 20-56.

Affirmation of the Prior Provisional Election of Group I Claims Subject Matter

Subject to the cancellation of claims 1-19 as noted in the prior section, applicant hereby affirms the prior provisional election of the subject matter of the Group I claims. Claims 36-40 have been withdrawn from consideration.

Withdrawn independent claim 36, from which withdrawn claims 37-40 depend, has been amended herein for conformity with claim 20, and applicant hereby affirmatively requests rejoinder of the method claims 36-40 of Group II under the applicable rejoinder provisions of MPEP §821.04 upon confirmation of allowable subject matter of the corresponding device claims in Group I.

Amendment of Claims

Claims 20, 27, 28, 31, 36, 41, 50 and 55 have been amended herein, to provide specific recital of the gastric occlusive technology of applicant's invention.

Claim 20 has been amended to recite "wherein said balloon in an inflated state has a diameter in a range of from 3 to 5 inches, said balloon is generally spherical in shape, and said multilayer film has a thickness of up to 10 mils. Such recital is supported by the original disclosure of the application at paragraphs [0024], [0031] and [0041].

Claim 27 has been amended to recite that the multilayer film "comprises up to 4 thermoplastic polymer film layers, optionally with adhesive between sealing film and thermoplastic polymer film layers." Such recital is supported by the original disclosure of the application at paragraph [0046].

Claim 28 has been amended to delete the term "about" before the upper thickness limit, consistent with the disclosure in paragraph [0026], wherein the upper limit in equivalent metric units is devoid of such limit.

Claim 31 has been amended to recite the thermoplastic polymer film thickness upper limit as being 5.0 mils, consistent with the disclosure in paragraph [0035].

Claim 36 has been amended consistently with claim 20, and accordingly has the same supportive disclosure in the original application as the latter claim.

Claim 41 has been amended to recite "said film comprising a multilayer film including: a layer of sealing film, having main top and bottom surfaces; and a layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the layer(s) of thermoplastic polymer film alone lacks such gas barrier character; wherein said balloon in an inflated state has a diameter in a range of from 3 to 5 inches, said balloon is generally spherical in shape, and said multilayer film has a thickness of up to 10 mils." Such recital is supported by the disclosure at paragraphs [0021], [0024], [0031] and [0041].

Claim 50 has been amended to recite "wherein the multilayer film comprises up to 4 thermoplastic polymer film layers, optionally with adhesive between sealing film and thermoplastic polymer film layers." Such recital is supported by the disclosure at paragraph [0046].

Claim 55 has been amended to recite "wherein said balloon is generally spherical in shape, wherein said film is a multilayer film having a thickness of up to 10 mils and includes up to 4 thermoplastic polymer film layers, optionally with adhesive between sealing film and thermoplastic polymer film layers, and wherein said film comprises (i) a layer of polyvinylidene chloride or EVOH polymer having a thickness of from about 0.25 to about 2.0 mils (0.00635 mm to 0.0508 mm), and (ii) a layer of polyurethane having a thickness of from about 2.0 to about 5.0 mils (0.0508 mm to 0.127 mm)." Such recital is supported by the original disclosure at paragraphs [0024], [0031], [0035] and [0046].

Accordingly, no new matter (35 USC 132) has been introduced in the amended claims.

Rejection of Claims on Reference Grounds, and Traversal Thereof

In the October 13, 2005 Office Action, claims 1-35 were rejected on various reference grounds, including:

a rejection of claims 1-17 under 35 USC 102 (b) as anticipated by Michaels et al. US patent 3,901,232;

a rejection of claims 1-17 under 35 USC 102 (b) as being anticipated by Mitchell et al. US patent 5,713,141;

a rejection of claims 1-17 under 35 USC 102 (b) as being anticipated by Bonk et al. US patent 6,082,025;

a rejection of claims 1-8, 10-11, 13-28, 30-31 and 33-35 under 35 USC 102 (b) as being anticipated by Bryant et al. US patent 5, 738, 657; and

a rejection of claims 9, 12, 29 and 32 under 35 USC 103 (a) as unpatentable for Bryant, as applied to claims 1 and 20, above.

Such rejections are traversed, in light of (i) the cancellation of claims 1-19 herein, mooting the rejections based on Michaels et al., Mitchell et al., and Bonk et al., and (ii) the amendments of claims 20, 27, 28, 31, 36, 41, 50 and 55 herein, to place claims 20-35 and 41-56 in condition for

allowance, obviating the rejections based on Bryant et al., and enable claims 36-40 to be rejoined under the applicable rejoinder provisions of MPEP §821.04.
Reconsideration therefore is requested, in light of the ensuing remarks.

Patentable Distinction of Claims 20-35 and 41-56 Over the Cited References

Although only Bryant et al. was cited against claims 20-35 in the October 13, 2005 Office Action, the salient teachings of all of the cited references of Michaels, Mitchell, Bonk and Bryant are set out below, together with distinguishing remarks concerning the patentable merit of the claims as amended herein.

The Michaels Disclosure

Michaels discloses a drug delivery device ingested in a bioerodible hollow container, e.g., a gel cap. The drug delivery device includes a strip of a solid or semi-solid membrane material that is attached by adhesive to an inflatable enclosure. The strip of membrane material contains a drug or drug mixture that diffuses from the strip as a sustained-release administration in vivo. The inflatable enclosure is initially in a deflated state and may be in the form of a "completely sealed tube,... envelope, flat bag, balloon and the like" (column 4, lines 17-19 of Michaels).

Michaels discloses that the inflatable enclosure "should be large enough to retain the device in the stomach, that is, slightly larger than the diameter of the pyloric canal which is about 1 cm to 4 cm, usually 2 cm in humans" (column 5, lines 9-12, of Michaels). The shape of the device "is usually tubular but other shapes such as oblong, oblate, prolate, spherical, halfcircle, and the like can be used" (column 5, lines, 58-59 of Michaels). The size of the device is further elaborated in the paragraph bridging columns 5 and 6 of the patent:

"... for humans the size of the inflated member will be about 1 cm in diameter to about 10 cm in length, usually about 2 cm by 4 cm. Other sizes such as 2 cm by 5 cm, 3.14 cm by 5 cm, 4 cm by 4 cm and the like are also within the mode and manner of the invention" (column 5, line 65 to column 6, line 3 of Michaels).

Michaels describes the inflatable member has being formed of a film about 0.2 mills to 100 mils thick, or more (column 6, lines 6-7) and describes use of combinations of materials in laminated

form, including, *inter alia*, polyurethanes and polyvinylidene chloride. At column 14, lines 2-6, Michaels describes an elipsoidal collapsible balloon with a minor axis of 3 cm and a major axis of 5 cm, formed from a copolymer of polyvinylidene chloride and polyvinyl chloride.

Michaels therefore provides no derivative basis for a balloon that is "generally spherical" with an inflated diameter of "in a range of from 3 to 5 inches" as recited in claim 20, since Michaels' disclosure of a size "slightly larger than the diameter of the pyloric canal which is about 1 cm to 4 cm, usually 2 cm in humans" is well below the lower limit of applicant's dimensional range.

Such fundamentally different dimensional characters is consistent with the fact that Michaels' smaller dimensions apply to a drug delivery device in which drug is dispensed from a permeable or microporous reservoir strip, whereas applicant's larger dimensions are applicable to a gastric occlusive device that is deployed to restrict stomach volume and thereby combat obesity.

Since all of applicant's claims 20-35 and 41-56 require inflated diameter "in a range of from 3 to 5 inches," and there is no motivation to increase the size of the Michaels device, claims 20-35 and 41-56 are patentably distinguished over Michaels.

The Mitchell Disclosure

Mitchell describes cushioning devices made from flexible membranes, for use in footwear. The membranes are formed into tubular enclosures or heel peds to form sealed structures containing an injected captive gas, and are either fully or partially encapsulated within the mid-sole or out-sole of footwear articles (column 8, lines 37-41 of Mitchell). As disclosed at column 9, lines 1-63 of Mitchell, the membrane may be formed of a combination material layers including a thermoplastic urethane layer and a layer formed of ethylene vinyl alcohol or polyvinylidene chloride.

A sandwich configuration including a first layer of thermoplastic urethane, a second intermediate layer of barrier material, and third layer of thermoplastic urethane is described at column 12, lines 58-61 of the patent, and such multilayer films may be coextruded at a thickness between 1 and 100 mils, as described at column 15, lines 1-12 of Mitchell. The captive gas can be hexafluoroethane, sulfur hexafluoride, or other gas that facilitates diffusional pumping, to maintain the pressure in the tubular enclosure or heel ped for a sustained period of time, such as two years (column 5, line 52 of Mitchell).

The flexible membrane teachings of Mitchell for footwear provide no basis whatsoever for the gastric occlusive device of applicant's claimed invention. Relative to footwear applications, Mitchell is simply non-analogous art having no pertinence to the particular problem with which the inventor was concerned. See MPEP 2173.05(g).

The Bonk Disclosure

Bonk discloses a pressurized bladder or cushioning device useful in footwear and hydropneumatic accumulators, although a broad range of applications is described at column 1, lines 9-33 of the patent, including footballs, basketballs, soccer balls, inner tubes, flotation devices such as tubes or rafts, medical equipment such as catheter balloons, components for furniture such as chairs and seats, bicycle and saddle parts, shin guards and helmets, furniture supports, lumbar supports, prosthetic and orthopedic devices, vehicle tires, and components of recreation equipment such as wheels for in-line or roller skates.

The bladder or cushioning device disclosed by Bonk has alternating layers of at least one fluid barrier material and at least one structural, elastomeric material (column 6, lines 61-65 of Bonk) with the barrier material including EVA copolymers, polyvinyl chloride, polyvinylidene polymers and copolymers such as polyvinylidene chloride, etc., as described at column 11, line 64 to column 12, line 51 of the patent, and the elastomeric material including polyurethane elastomers and other elastomeric material species (column 7, lines 30-45 of Bonk).

As described at the column 7, lines 5-10 of Bonk,

"The microlayer polymeric composite should have at least about 10 layers. Preferably, the microlayer polymeric composite has at least about 20 layers, more preferably at least about 30 layers, and still more preferably at least about 50 layers. The microlayer polymeric composite can have thousands of layers..."

As in the Mitchell patent, Bonk describes membrane enclosures containing a captive gas for a relatively long period of time, "for at least about two years" (column 15, lines 41-42), in footwear applications.

Bonk provides no teaching or suggestion of a balloon with an inflated diameter of "in a range of from 3 to 5 inches" and there is no teaching or suggestion of gastric occlusion that would motivate such specific dimensions.

Since all of applicant's claims 20-35 and 41-56 require a balloon with an inflated diameter "in a range of from 3 to 5 inches," and there is no teaching or suggestion of gastric occlusion that would motivate such specific dimensions, claims 20-35 and 41-56 are patentably distinguished over Bonk.

Additional basis for distinction over Bonk resides in claims 1 (reciting an effervescent material, such material having no basis in Bonk), and claims 27, 50 and 55 (reciting up to 4 thermoplastic polymer film layers in the laminate, whereas Bonk requires at least 10 layers and up to "thousands of layers," again reflecting the absence of any gastric occlusive teaching or other relevant disclosure in Bonk for applicant's claimed invention).

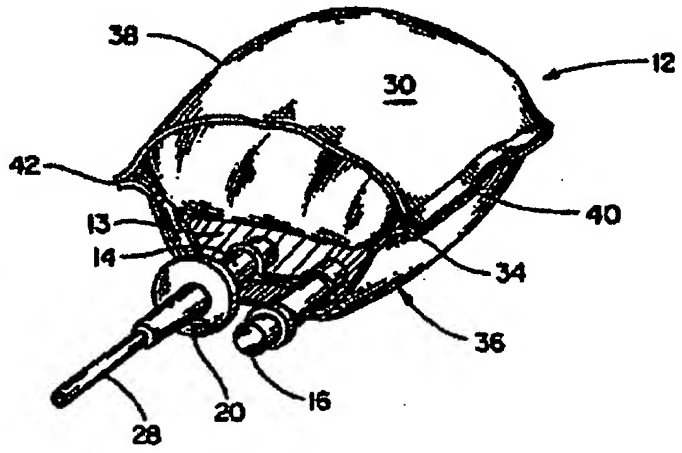
The Bryant Disclosure

Bryant describes a combination sleeve and bladder assembly, in which the sleeve accommodates insertion of an IV bag, and the bladder member is inflatable by gas-generating chemical means therein, to expand and apply continuous pressure against the IV bag, thereby ensuring positive pressure, continuous flow of IV fluid to a patient. The gas-generating chemical means to include reactants that are segregated from one another within the bladder, and in one disclosed embodiment a co-reactant is contained in a capsule, which is manually breakable to expose the co-reactive to another chemical material for reaction therebetween.

The bladder is formed of flexible plastic material that can include at least two laminated layers of material having different material stiffness. The patent describes a bladder formed of a laminate including a one mil sheet of polyvinylidene chloride, "laminated or coated to 20 mil of polyurethane, in either of two forms... the layer 56 of polyvinylidene chloride is laminated to the inner surface of a 20 mil layer 58 of polyurethane [and] in FIG. 11 the 1 mil layer 56 of polyvinylidene chloride is laminated and embedded between two 10 mil layers 58a of polyurethane" (column 8, lines 44-50 of Bryant).

The sleeve portion of the sleeve and bladder assembly is stated that column 7, lines 49-50 to be "of a size to receive the 100 cc flexible bag 13 of saline solution." The size of the bladder is not specifically described. The perspective view in FIG. 2 of the patent shows the inflated bladder in a sleeve and bladder assembly in which the sleeve retains an IV bag 13 beneath the bladder 38, as reproduced below.

FIG. 2



It is apparent that the inflated bladder of Bryant is not "generally spherical" in character as required by all of applicant's claims, but rather has a flattened rectangular pillow shape, consistent with the fact that Bryant's device is an *ex vivo* pressure applicator for fluid dispensing, and not a device to be employed *in vivo* to combat obesity as is applicant's invention.

Further, Bryant teaches (column 8, lines 44-50) a bladder formed of a laminate including a 1 mil sheet of polyvinylidene chloride, "laminated or coated to 20 mil of polyurethane, in either of two forms... the layer 56 of polyvinylidene chloride is laminated to the inner surface of a 20 mil layer 58 of polyurethane [and] in FIG. 11 the 1 mil layer 56 of polyvinylidene chloride is laminated and embedded between two 10 mil layers 58a of polyurethane."

Thus, the Bryant laminate is 21 mils in thickness, whereas all of applicant's claims 20-35 and 41-56 require the multilayer film to have a thickness that does not exceed 10 mils (see independent claims 20, 41 and 55, reciting that the multilayer film has "a thickness of up to 10 mils"), again underscoring the fact that Bryant's device is an *ex vivo* pressure applicator for fluid

dispensing, and not in any way suggestive of a gastric occlusive device that is disposed in the gastric cavity inside the body, as a therapeutic intervention for obesity treatment.

Claims 20-35 and 41-56 are therefore patentably differentiated over Bryant.

CONCLUSION

All pending elected claims 20-35 and 41-56 as amended herein are now in form and condition for allowance. It therefore is respectfully requested that such claims now be allowed, and that non-elected claims 36-40 now be rejoined with such claims 20-35 and 41-56 under the applicable rejoinder provisions of MPEP §821.04.

Respectfully submitted,

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